EFFICACY REVIEW

Product: **RAMIK-A, ALL-WEATHER BAIT, Kills Rats and Mice**

Date: October 25, 2002

EPA File Symbol: 61281-GN (30)

DP Bar code: D284383

Chemical Code: 067701

Formulation: Bait Formulation
0.005% Diphacinone

Purpose for Review: The purpose for this review is to determine if RAMIK-A is efficacious as a rat or mouse control product in wet or dry environments.

MRID(s):

45650804 N. Svircev. 2002. RAMIK-A, Norway Rat Anticoagulant Technical and Concentrate Dry Bait Laboratory Test Method. Unpublished Report. 124pp.

45650805 N. Svircev. 2002. RAMIK-A, House Mouse Anticoagulant Technical and Concentrate Dry Bait Laboratory Test Method. Unpublished Report. 43pp.

Good Laboratory Practices: Yes

Branch Supervisor: Meredith Laws, Branch Chief

Team Reviewer: John Hebert, Acting Product Manager -PM Team 04

IRB Reviewer: Geraldine R. McCann, Environmental Protection Specialist

BACKGROUND: HACCO, INC. has applied for a new pesticide registration of a 0.005% diphacinone product called RAMIK - A All Weather Bait Kills Rats and Mice. The new product label packaging includes a range of sizes for the 2 ounce bait from 8 ounces to 100 pounds. Efficacy tests were conducted according to the guidelines specified in the Standard Norway Rat Anticoagulant Wax Block and Wax Pellet

Laboratory Test Method 1.213, the Standard Norway Rat Anticoagulant Technical and Concentrated Dry Bait Laboratory Test Method 1.221, the Standard House Mouse Anticoagulant Wax Block and Wax Pellet Laboratory Test Method 1.214, and the Standard House Mouse Anticoagulant Technical and Concentrated Dry Bait Laboratory Test Method 1.225. This is a review for two efficacy tests and a product label.

REVIEW OF DATA:

1. **45650804** N. Svircev. 2002. RAMIK-A, Norway Rat Anticoagulant Technical and Concentrate Dry Bait Laboratory Test Method. Unpublished Report. 124pp.

DISCUSSION: This study was conducted to determine the efficacy of the RAMIK-A on male and female Sprague-Dawley laboratory rats from the Sasco Laboratories, Omaha, Nebraska.

Pretest acclimation of the rats was 10 days, actual test period lasted 15 days with the remaining treated rat dying on day 12. Two (2) control rats died on day 9 and day 11, respectfully. The control rats were fed Standard OPP diet for the duration of the 15 day test with 5 days posttreatment.

The weathered bait was prepared and weathered at 90-100% humidity. The temperature fluctuated between 98.6 and 100.4° F (37 to 38° C). No time frame was stated in the WEATHERIZATION OF THE TEST MATERIAL section text for how many days the bait was weatherized. This was not mentioned until page 11 (under the TEST PERIOD section). Exact temperatures and humidity ranges for the bait preparation and weatherization are not included in the submission.

Results of the rat test are summarized below:

Table 1. - Group 1-Rats on Fresh Bait

Pretest Weights **Bait Consumption and Mortality**

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Fresh Bait Consumed (g)	Total Bait Consumption (g)
M (10)	250.42	1525.4	959.9	2485.3
F (10)	228.50			Percent Fresh Bait

Total (20)	Group Difference 21.92	**100% Mortality**	Consumed = **38.63%**

Table 2. - Group 2-Rats on Weatherized Bait

Pretest Weights		**Bait Consumption and Mortality**		
Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Fresh Bait Consumed (g)	Total Bait Consumption (g)
M (10)	250.75	1865.7	874.7	2740.4
F (10)	228.09	**100% Mortality**		Percent Weatherized Bait Consumed. = **31.92%**
Total	Group Difference 22.66			

Table 5. Group 3-Rats on Control Bait

Pretest Weights		**Bait Consumption and Mortality**
Sex	Average Group Weight (g)	OPP Diet Consumed (g)
M (10)	259.40	7651.8
F (10)	232.31	**10% Mortality**
Total	Group Difference 27.09	

Mortality in both treated groups exceeded the 80-90% for anticoagulant weatherized bait and anticoagulant fresh bait. The control group experienced 10% mortality which did not appear to be sick from poisoning.

The maximum acceptable difference in average weights between sexes should only be 50 grams according to the Standard Norway Rat Anticoagulant Wax Block and Wax Pellet Laboratory Test Method 1.213. The difference in average weights between sexes was a total of 71.67 g. This criteria of the test guidelines was not met; however, the rest of the criteria are acceptable.

2. **45650805** RAMIK-A, House Mouse Anticoagulant Technical and Concentrate Dry Bait Laboratory Test Method.

DISCUSSION: This study was conducted to determine the efficacy of the RAMIK-A on male and female mice. The laboratory mice were of the CF-1 strain from the Sasco Laboratories, Omaha, Nebraska. They reportedly weighed between 15 and 35 grams. Exact weights of individual animals pre-test was not included in the submission. The average body weight of each sub-group (5 animals) was determined at the beginning of the test (see tables below). The maximum acceptable difference in average weights between sexes allowed is 5 g according

to the Standard House Mouse Anticoagulant Wax Block and Wax Pellet Laboratory Test Method 1.214, and the difference between the pre-test weights was not discussed in the report.

The weathered bait was prepared and weathered at 90-100% humidity. The temperature fluctuated between 98.6 and 100.4° F (37 to 38° C). No time frame was stated in the WEATHERIZATION OF THE TEST MATERIAL section text for how many days the bait was weatherized. This was not mentioned until page 11 (under the TEST PERIOD section). Exact temperatures and humidity ranges for the bait preparation are not included in the submission.

Pretest acclimation of the mice was 3days, actual test period lasted 15 days with the remaining 2 treated mice dying on day 11. The control mice were fed their Standard OPP diet for 9 days (15 day test with 5 days posttreatment) after the last 2 treated mice died.

Results of the mouse test is summarized below:

Table 1.-Group 1-Mice on Fresh Bait

Pretest Weights		**Bait Consumption and Mortality**		
Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Fresh Bait Consumed (g)	Total Bait Consumption (g)
M (10)	26.80	400.1	261.1	661.2
F (10)	24.35	**100% Mortality**		Percent Fresh Bait Consumed =**39.49 %**
Total (20)	Group Difference 2.45			

Table 2.-Group 2-Mice on Weatherized Bait

Pretest Weights		**Bait Consumption and Mortality**		
Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Fresh Bait Consumed (g)	Total Bait Consumption (g)
M (10)	27.75	383.0	174.5	557.5
F (10)	25.35	**100% Mortality**		Percent Weatherized Bait Consumed. = **31.3 %**
Total (20)	Group Difference 2.40			

Table 3.-Group 3-Mice on Control Bait

Pretest Weights		**Bait Consumption and Mortality**
Sex	Average Group Weight (g)	OPP Diet Consumed (g)
M (10)	25.60	2428.8

F (10)	25.15	**0 % Mortality**
Total (20)	Group Difference 0.45	

Label Review:

1. The statement on the front of the label for "Mold and Moisture Resistant" has no data to support this claim and should be deleted.

2. The First Aid statement are not formatted per PR Notice 2001-1. In the **If Swallowed** section, "for" is missing between "doctor" and "treatment". The following statements should be added to this section:

   ·Have person sip a glass of water if able to swallow.
   ·Do not induce vomiting unless told to do so by the poison control center or doctor.
   ·Do not give anything by mouth to an unconscious person.

3. **If on Skin** should be changed to say:

   ·Rinse skin immediately with plenty of soap and water.

4. **If Inhaled** should be included because pellets may break down and there may be dust present in the package that could be aspirated. Please include If Inhaled with the following bullets:

   ·Move person to fresh air.
   ·If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
   ·Call a poison control center or doctor for further treatment advice.

CONCLUSION(S):

1. The RAMIK-A, Norway Rat Anticoagulant Technical and Concentrate Dry Bait Laboratory Test Method (MRID # 45650804) submitted in support of the new product is acceptable. The differences in the male and female rat weights pretest (71.4g) was greater that the recommended difference (50 g). This deviation is not deemed to affect the scientific integrity of the study. The mortality was 100% for both treated groups and the bait consumption was more than the 33% required for "fresh" anticoagulant bait and more than the 25% required for the weatherized bait in the Standard Norway Rat Anticoagulant Wax Block and Wax Pellet Laboratory Test Method 1.213.

2. The RAMIK-A, House Mouse Anticoagulant Technical and Concentrate Dry Bait Laboratory Test Method. RAMIK-A, All Weather Bait (MRID # 45650805) submitted in support of the new product is acceptable. No deviations were found in this study, and even though the individual weights were not submitted to determine pretest weights, the group weights pretest were very close. The mortality was 100% for both treated groups and the bait consumption was more than the 33% required for "fresh" anticoagulant bait and more than the 25% required for the weatherized bait in the Standard House Mouse Anticoagulant Wax Block and Wax Pellet Laboratory Test Method 1.214.

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